UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte BRIAN SEED and JOHN C. SEED

Appeal No. 2004-0898
Application No. 09/735,024

ON BRIEF

Before SCHEINER, MILLS, and GREEN, Administrative Patent Judges.

GREEN, Administrative Patent Judge.

REMAND TO THE EXAMINER

This case is remanded to the examiner to clarify and analyze the relationship of the instant application to parent application 09/198,874, now Patent No. 6,159,993, and parent application 08/680,684, now U.S. Patent No. 5,561,399.

Claims 55-71 of the instant are pending and before us on appeal. Claims 55 and 70 are representative, and read as follows:

55. A method for reducing coronary artery stenosis by at least 20% in a mammal comprising the administration to said mammal of a combination of (a) a composition comprising eicosapentaeneoic acid or docosaheaxaeneoic acid and (b) a cholesterol synthesis or transfer inhibitor, in combination with limiting fat or cholesterol

intake, whereby a serum LDL concentration of less than or equal to 70 mg/dl is achieved.

70. The method of claim 55, wherein said method further comprises administering to said mammal buspirone.

The '993 patent issued on December 12, 2000. Claims 1, 18, 33 and 36 appear to be particularly relevant to the claims on appeal, and read as follows:

1. A method for treating inadequate myocardial function in a mammal comprising the administration to said mammal of a combination of (a) a compound comprising eicosapentaeneoic acid or docosahexaeneoic acid and (b) a cholesterol synthesis or transfer inhibitor, in combination with limiting fat or cholesterol intake, whereby a serum LDL concentration of less than or equal to 70 mg/dl is achieved and whereby said treatment results in a rapid and enduring reduction in a symptom of inadequate myocardial function.

18. A medication comprising (a) a compound comprising eicosapentaeneoic acid or docosahexaeneoic acid and (b) a cholesterol synthesis or transfer inhibitor.

33. The medication of claim 18, wherein said medication reduces coronary artery stenosis by at least 20%.

36. A method for reducing coronary artery stenosis by at least 20% in a mammal, comprising the administration to said mammal of a cholesterol-lowering therapeutic combined with limiting fat or cholesterol intake, whereby a serum LDL concentration of less than or equal to 75 mg/dl is achieved.

The '339 patent issued on January 19, 1999. With respect to that patent, claims 1, 3 and 5 appear to be particularly relevant, and read as follows:

1. A method for treating heart disease in a mammal comprising administering buspirone to said mammal in an amount which reduces a heart disease symptom.

3. The method of claim 1, wherein said heart disease symptom is a coronary artery stenosis.

5. A medication comprising (a) a compound comprising eicosapentaeneoic acid or docosahexaeneoic acid and (b) a cholesterol synthesis or transfer inhibitor, wherein said medication further comprises buspirone.

The '993 and '339 patents raise two issues that need be addressed by the examiner on the record.

First, the rejection of the claims 55-71 under 35 U.S.C. § 103(a) over the combination of Sassen, Vane, Lee, Watts and Demopulos, the rejection of claims 55-60, 62, 63, 65-68, 70 and 71 under 35 U.S.C. § 112, first paragraph, as well as the rejection of claims 55-71 under 35 U.S.C. § 112, second paragraph, would appear to bring into question the patentability of the claims of the '993 patent and the '339 patent.

The examiner rejected claims 55-60, 62, 63, 65-68, 70 and 71 under 35 U.S.C. § 112, first paragraph, on the grounds that the specification, while being enabling for cholesterol synthesis or transfer inhibitors as disclosed on page 7 of the specification, "does not reasonably provide enablement for other cholesterol synthesis or transfer inhibitors." Examiner's Answer, page 8. But as can seen above, both the '993 and '339 patent claims contain the language "a cholesterol synthesis or transfer inhibitor," which has not been limited in the manner suggested by the examiner.

The examiner also rejected claims 55-71 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that appellant regards as the invention. According to the rejection, "[t]he expression 'cholesterol ... transfer inhibitor' in claim 55 renders

the claims indefinite as to the compounds encompassed thereby." Examiner's Answer, page 5. Again, the objected to language appears in the claims of both '993 and '339 patents.

Finally, claims 55-71 stand rejected appeal under 35 U.S.C. § 103(a) over the combination of Sassen, Vane, Lee, Watts and Demopulos. Claim 55 of the instant application is drawn to a method of reducing coronary artery stenosis by at least 20% in a mammal by administering a combination of (a) a composition comprising eicosapentaeneoic acid or docosaheaxaeneoic acid and (b) a cholesterol synthesis or transfer inhibitor, in combination with limiting fat or cholesterol intake, whereby a serum LDL concentration of less than or equal to 70 mg/dl is achieved.. Claim 1 of the '993 patent comprises the same method, except it is drawn to a method of treating inadequate myocardial function. The term "inadequate myocardial function," however, would appear to encompass coronary artery stenosis, see, e.g., Specification, page 4 ("For example, the medication may also be used to restore blood flow to infracted myocardium or improve myocardial function (for example, perfusion) . . ."), and thus the rejection as set forth by the examiner would appear to be equally applicable to claim 1 of the '993 patent.

In addition, claim 18 of the '993 patent is drawn to a medication comprising eicosapentaeneoic acid or docosaheaxaeneoic acid and a cholesterol synthesis or transfer inhibitor. That composition is the same composition required by pending claim 55. Similarly, claim 5 of the '399 patent is drawn to the same medication further comprising buspirone, which would be the same as the

composition required by pending claim 70. It is unclear from the record why if the medications (products) are patentable, the method of using those medications is not.

While we acknowledge that the examiner may issue a rejection, such as those set forth above, if appropriate, the rejection would appear to require the signature of the Technology Center Director. Cf. Manual of Patent Examining Procedure (MPEP) § 2307.02 (8th ed., August 2001). From our review of the file, as well as the Examiner's Answer, such a signature does not appear to have been obtained. Upon return of the application, the examiner should review the above rejections in view of the prosecution of the above two patents, and if any of the above rejections are maintained, obtain the signature of the Technology Center Director or explain on the record why such a signature is not required.

Second, there appear to be obviousness-double patenting issues that do not seem to have been considered on the record. In this regard, we note that the instant application is a continuation of the applications that issued as the '993 and '339 patents. For the reasons noted above with respect to the rejection of claims under 35 U.S.C. § 103(a) over the combination of Sassen, Vane, Lee, Watts and Demopulos, it would appear that such issues may exist. Upon return of the application, the examiner should consider whether rejection of the pending claims under the judicially made doctrine of obviousness-type double patenting over the claims of the '993 and/or the '339 patents is appropriate, and if not, explain on the record the reasons why the obviousness-type double patenting rejection is not appropriate.

FUTURE PROCEEDINGS

This remand to the examiner pursuant to 37 CFR § 41.50(a)(1) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)) is made for further consideration of a rejection. Accordingly, 37 CFR § 41.50(a)(2) applies if a supplemental examiner's answer is written in response to this remand by the Board.

This application, by virtue of its "special" status, requires an immediate action. MPEP § 708.01 (7th ed., rev. 1, February 2000). It is important that the Board be informed promptly of any action affecting the appeal in this case.

REMANDED

TONI SCHEINER)
Administrative Patent Judge)
)
)
DEMETRA MILLS) BOARD OF PATENT
Administrative Patent Judge) APPEALS AND
)
) INTERFERENCES
LORA M. GREEN)
Administrative Patent Judge)

LMG/jlb

Clark & Elbing LLP
101 Federal Street
Boston, MA 02110